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SPIRIT II STUDY: EVALUATION OF THE XIENCE V EVEROLIMUS ELUTING CORONARY STENT IN THE TREATMENT OF PATIENTS WITH DE NOVO NATIVE CORONARY ARTERY LESIONS

ACC Poster Contributions
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Background: The SPIRIT II study is a continuation in the assessment of the safety and performance of the XIENCE V Everolimus Eluting Coronary Stent (EES) in the treatment of patients with a maximum of 2 de novo native coronary artery lesions (from 2.5 mm to 4.25 mm in diameter and ≤ 28 mm in length).

Methods: In the SPIRIT II study, the EES is compared to the TAXUS Paclitaxel-Eluting Coronary Stent System (PES). The primary endpoint is in-stent late loss (LL) at 180 days. The secondary analyses include in-segment LL, proximal and distal LL, in-stent % volume obstruction (%VO), in-stent % diameter stenosis and angiographic binary restenosis at 180 days and 2 years. Ischemia Driven Major Adverse Cardiac Events (MACE) are assessed through 5 years.

Results: 300 patients were randomised 3:1 (EES: PES) at 28 sites in Europe, New Zealand and India.At 180 days, the mean in-stent LL (analysis lesion, intent-to-treat population) was significantly lower for the EES compared to the PES, 0.11±0.27mm vs 0.36±0.39mm (non-inferiority $p<0.0001$, superiority $p<0.0001$). At 2 year follow up the in-stent LL was no longer significantly different; 0.33±0.37mm in EES vs. 0.34±0.34mm in PES. IVUS results showed that in EES the neo-intimal volume was 8.4 mm and the % VO was 5.2% vs 11.6 mm and 5.8 % in PES. However despite this modest increase in LL and neo-intima in the EES, analysis of 2-year clinical results showed that the MACE rates for the procedure were 6.6% in EES vs 11.0% in PES. At 3 years, compared to the PES, the EES resulted in fewer cardiac events, including reduction in cardiac death (0.5% vs 4.3%, $p=0.056$), in myocardial infarction (3.6% vs 7.2%), ischemia-driven target lesion revascularization (4.6% vs 10.1%), and overall MACE (7.2% vs 15.9%, $p=0.053$). By ARC definition, definite/probable stent thrombosis was 1.0% in EES and 2.9% in PES.

Conclusion: Based on the protocol design and statistics, EES showed non-inferiority and superiority to PES in terms of LL. Additionally, 3 year data shows a consistent reduction in clinical events for EES versus PES and low stent thrombosis rate for EES. The four-year clinical results will be presented.